Irvine Scientific DEC - 7 2000 October 20, 2000

510(k) SUMMARY AS REQUIRED BY SECTION 807.92(c)

Submitted by:

Irvine Scientific Sales Co., Inc.
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Contact: Wendell Lee, Pharm. D.
Vice President, Regulatory Affairs

Date Submitted: October 20, 2000

Device Identification:

Trade Name:	Dextran Serum Supplement (DSS)
Common Name:	In vitro embryo culture protein supplement
Classification Name:	Reproductive Media (21 CFR 884.6180)
Product Code:	85MQL

Predicate Device:

Please notice that this class of product is covered under the Notice of Final Rule, 63 FR 48428, Docket number 97N-0335. Serum Substitute Supplement (SSS) is also used as a predicate.

Description:

Dextran Serum Supplement consists of human serum albumin from therapeutic-grade source material (50 mg/mL) dextran from pharmaceutical-grade source material (20 mg/mL) in a sterile saline solution.

Intended Use:

Dextran Serum Supplement is intended for use in assisted reproductive procedures that require protein supplementation. These procedures include in vitro fertilization, embryo culture and growth, and embryo cryopreservation.

Technological Characteristics:

Depending upon the procedure used, an appropriate amount of pre-warmed, equilibrated DSS is added to the culture dish and support medium. After the desired stage of embryo development is achieved, the embryo is removed from the culture dish, placed into a HEPES-buffered transfer medium, and implanted into the patient. DSS is not intended to contact the patient directly.

Performance Data:

DSS is assayed by mouse embryo assay prior to release to market. This assay assures that the product is both functional for its intended use, the support of embryonic growth, and that no toxic components are present in the formulation.

Additional Information:

Mouse embryo, endotoxin, and sterility testing will be performed as a condition of release for this product. Results of all release assays performed will be indicated on the labeling and reported on a lot-specific certificate of analysis.

Conclusion:

The conclusion from performance testing as well as a review of the historical information contained in professional literature shows that Dextran Serum Supplement is suitable for its intended use and meets the criteria outlined in the Notice of Final Rule, 63 FR 48428, Docket number 97N-0335.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 7 2000

Wendell Lee, Pharm. D.
Vice President
Quality Systems and Regulatory Affairs
Irvine Scientific Sales, Co., Inc.
2511 Daimler Street
SANTA ANA CA 92705

Re: K003448
Dextran Serum Supplement (DSS)
Dated: October 20, 2000
Received: November 06, 2000
Regulatory Class: II
21 CFR §884.6180/Procode: 85 MQL

Dear Dr. Lee:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

INDICATIONS FOR USE STATEMENT (page 1 of 1)

510(K) Number: K003448

Device Name: Dextran Serum Supplement

Indications for Use:

DSS is designed for those assisted reproductive procedures that require the use of a protein supplement. In particular, DSS is intended for use in gamete-processing, in vitro fertilization, in vitro embryo culture to the desired stage of embryo development, and for the cryopreservation of human embryos and sperm.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003448

Prescription Use ✓
(Per 21 CFR 801.109)